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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,183	11/10/2003	Stephen D. Hurst	DX01088KB	4790

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
JIANG, DONG	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/705,183	HURST ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/10/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's election without traverse of Invention VIII, represented by the original claim 22, filed on 19 September 2006 is acknowledged.

Applicant's amendment filed on 19 September 2006 is acknowledged and entered. Following the amendment, the original claims 15-27 are canceled, and the new claims 28-32 are added.

Currently, claims 28-32 are under consideration.

Formal Matters:

Information Disclosure Statement

Applicant's IDS submitted on 11/10/03 is acknowledged and has been considered. A signed copy is attached hereto.

Priority acknowledgement

This application claims benefit of U.S. application 09/836,385 filed on 4/17/01, and U.S. provisional application 60/198,488 filed on 4/18/00, which is acknowledged.

Specification

Title

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

The specification is objected to because the status of U.S. Application 09/836,385, which has been issued as U.S. Patent No. 6,676,939, has not been updated yet.

Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28, 29, 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is indefinite for failing to adequately and specifically identify the protein, "an IL-174", from which the subject matter of the current invention was derived. The claim does not require that "an IL-174" has any specific sequence structure (such as SEQ ID NO:2 as disclosed in the specification) or functional activity, and the specification does not define the term. As such, the claim merely defines a protein by an arbitrary name, which is not meaningful as to the identity of the protein. Further, it has been shown that the IL-174 of SEQ ID NO:2 is also called "IL-17E" by others in the art. It is, therefore, necessary that the applicant clearly defines the term "an IL-174" by sufficient identifying characteristics so as to clearly and distinctly indicate the polypeptide that is the subject of the invention. The claim is further indefinite for the recitation "an IL-174 *agonist*". As neither the structure nor the function of "an IL-174" is clearly defined, the agonist thereto cannot be determined, and the metes and bounds of the claim, therefore, cannot be determined.

Claim 29 is similarly indefinite for the recitation "a human IL-174 protein".

The remaining claims are included in this rejection because it is dependent from the specifically mentioned claims without resolving the indefiniteness issue belonging thereto.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to a method of treating a Helminth infection and infectious diseases known to be treatable with the human IL-174 protein of SEQ ID NO:2, does not reasonably provide enablement for claims to a method of treating any or all "infectious diseases" (claim 28, for example), or "parasitic infection" (claim 31, for example) with "an IL-174 agonist" of any kind. The specification does not enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 28-30 are directed to a method of treating an infectious disease, which reads on any or all infectious diseases; and claim 31 is directed to a method of treating a parasitic infection, which reads on any or all parasitic infection. However, the specification merely mentions that IL-174 can be use for treating, among many other diseases/conditions, a parasitic infection including Helminth (page 2, lines 35-36), and provides no working example of any kind, which associates with any infectious disease treatment. Prior art search reveals that while IL-25/IL-17E (same as applicants IL-174) may be useful in treating certain infectious diseases, it may not suitable for the treatment of others. For example, a recent study by Fallon et al. (J. Exp. Med., 2006 Apr 17; 203(4):1105-16) demonstrates that administration of rIL-25 to helminth infected mice induces rapid worm expulsion (abstract, Figure 2, and the paragraph bridging pages 1107 and 1108). However, another study by Na et al. (US 2006/0142558 A1) reports that *antagonizing IL-25* will be therapeutically useful in treating diseases/conditions including, among others, certain parasitic infections (such as leishmaniasis, toxoplasma infection and trypanosome infection), certain fungal infection, and certain intracellular bacterial infection (the paragraph bridging pages 24-25). It is, therefore, clear that IL-25 (or IL-174) is not suitable for treating any or all infectious diseases, or for even just any parasitic infection. The specification provides no instruction or guidance as to how any or all infectious diseases or parasitic infections can be treated by the IL-174. Given the fact that "infectious diseases" or "parasitic infections" encompasses a number of diseases/conditions caused by many distinct pathological organisms, and through different mechanisms, it is not predictable as to which specific infectious disease would benefit from the IL-25/IL-174 treatment. In the absence of additional evidence regarding the therapeutic application of IL-25/IL-174 in treating any other infectious disease, it would

require undue experimentation to practice the invention in a manner commensurate in scope with the claims.

With respect to "an IL-174 agonist" in claim 28, it reads on a functional equivalent of the IL-174, as there is no structural limitation associated with said agonist, which, therefore, can be any or many things besides the IL-174 or polypeptide variants thereof, such as agonist antibodies to the IL-174 receptor, and small chemical molecules. Thus the claims encompass a genus of molecules with broad structural diversity. However, the specification merely discloses one IL-174 with a particular amino acid sequence, and no other IL-174 agonist of any kind meeting the limitation of the claim was ever identified or particularly described in the specification. Therefore, it is impossible to predict the structures of the agonists encompassed by the claimed genus. Further, the specification provides no instruction or guidance to teach how to make those agonists meeting the limitation of the claim, and therefore, it does not reasonably provide enablement commensurate in scope with the claim to "an IL-174 agonist". As one skilled in the art would not know how to make the encompassed antagonists in its full scope based on the instant disclosure, the artisan would not be able to practice the claimed method in a manner commensurate in scope with the claims, and it would require undue experimentation.

Due to the large quantity of experimentation necessary to determine which "infectious disease" or "parasitic infection" is suitable for IL-25/IL-174 treatment, and to identify additional IL-174 agonists, to generate the infinite number of agonists thereto as recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the state of the prior art indicating not all infectious diseases or parasitic infections can be treated with IL-25/IL-174, the unpredictable and complex nature of the invention, and the breadth of the claims which embraces all infectious diseases and/or parasitic infections, and a broad class of molecules with extreme structural diversity ("an IL-174 agonist"), and fails to recite any structural or functional limitation, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claims 28, 29, 31 and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 28 is directed to a method of treating an infectious disease with *an IL-174 agonist*, which reads on a functional equivalent of any or all molecules having the "agonizing" activity of IL-174, and thus the claim encompass a genus of molecules with broad structural diversity, for example, agonist antibodies to the IL-174 receptor, and small chemical molecules. However, the specification merely discloses one IL-174 polypeptide of SEQ ID NO:2, and no other agonist of said polypeptide meeting the limitation of the claim was ever identified or particularly described in the specification.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, with respect to "an IL-174 agonist", the only factor present in the claims is a "functional" characteristic, i.e., an IL-174 *agonist*, which structure is not defined. Therefore, with the exception of the IL-174 polypeptide of SEQ ID NO:2, the skilled artisan cannot envision the sequence structure of the encompassed PRO10272 polypeptides or the antagonists thereto. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived.

See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

In the instant application, only the IL-174 polypeptide SEQ ID NO:2, but not the full breadth of the claims ("an IL-174 agonist") meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Art:

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Fallon et al. (J. Exp. Med., 2006 Apr 17; 203(4):1105-16) teaches that that administration of rIL-25 to helminth infected mice induces rapid worm expulsion (abstract, Figure 2, and the paragraph bridging pages 1107 and 1108).

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dong Jiang, Ph.D.
Patent Examiner
AU1646
11/22/06